AMENDMENT

IN THE CLAIMS

Please amend the claims as indicated in Appendix A submitted herewith according to the revision to 37 C.F.R. § 1.121 concerning a manner for making claim amendments.

REMARKS

Claims 1-3 are presently pending in the captioned application with claims 1-3 being amended.

Claims 1-3 have been amended to delete the term "or more" from the claims in response to a new matter rejection. Claim 3 has been amended to recite that a solution of acetic acid is 4% in which a precipitate containing crude proteoglycan is dissolved. Support for the 4% acetic acid solution can be found in the specification at page 5, line 2 from the bottom. No new matter within the meaning of § 132 has been added by either the deletion of the phrase "or more" or by the recitation of a 4% acetic acid solution.

The previous anticipation rejections have been withdrawn in the outstanding Office Action and are noted with appreciation.

Accordingly, Applicant respectfully requests the Examiner to enter the amendments, reconsider the rejections in view of the arguments and allow all claims pending in this application.

1. Rejection of Claims 1-3 under 35 U.S.C. § 112, ¶ 1

The Office Action rejects claims 1-3 under 35 U.S.C. § 112, ¶ 1 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention. The Office Action states:

> Claims 1-3 are directed to a method for preparation of crude proteoglycan comprising extracting cartilage with a solution of acetic acid of 4% or more to obtain crude proteoglycan. The specification indicates that the desirable concentration of the acetic acid eluting solvent is approximately 4% (page 4, last paragraph) and the Examples also indicates 4% acetic acid is used to extract the crude proteoglycan from cartilage (page 5). However, the specification does not describe the use of acetic acid at a concentration higher than 4%. Furthermore, there is no example demonstrating the advantage of using higher concentration (>4%) of acetic acid. Since the specification does not provide sufficient description of using acetic acid at a concentration higher than 4%, one skilled in the art would not know the advantage of using higher concentration of acetic acid. The lack of description of the effect of acetic acid at a concentration >4% in extracting proteoglycan, and the lack of representative species for the concentrations greater than 4% as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Applicant respectfully traverses the rejection. However, in the interest of advancing prosecution, Applicant has deleted the phrase "or more" from the claims without disclaimer or prejudice as to the subject matter encompassed within the phrase. Therefore, the rejection over the phrase "or more" is moot.

Accordingly, Applicant respectfully submits that claims 1-3 as amended satisfy the requirements under § 112, ¶ 1 and do not contain any new matter and therefore requests withdrawal of the outstanding § 112, ¶ 1 rejection.

2. **Rejection of Claim 3 under 35 U.S.C. § 112, ¶ 2**

The Office Action rejects claim 3 under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office Action states:

> Claim 3 is indefinite because the claim recites dissolving the precipitate containing crude proteoglycan in a solution of acetic acid, but it does not indicate what concentration of the acetic acid solution is used.

Applicant has amended claim 3 to recite that the precipitate containing crude proteoglycan in a solution of acetic acid is 4%.

Therefore, claim 3 particularly points out and distinctly claims the subject matter of the presently claimed invention.

Accordingly, Applicant respectfully submits that claim 3 is definite and therefore requests withdrawal of the outstanding rejection.

3. **Rejection of Claim 1 under 35 U.S.C. § 103(a)**

The Office Action rejects claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Miller et al. (Biochemistry 11, 4903-4909 (1972)). The Office Action states:

> Miller et al. teach a method for preparing collagen, where the proteoglycan components are removed from the fresh cartilage slices by first extraction with 0.05 M Tris, 1.0 M NaCl, pH 7.5 for 5 successive days, and then extracting with 0.5 M (corresponding to 3%) acetic acid employing the same protocol as for the neutral salt (page 4904, left column, paragraph 4; claim 1). Although Miller et al. do not disclose the use of 4% acetic acid (corresponding to 0.667 M) in extracting proteoglycan, at the time of invention was made, it would have been obvious to one of ordinary skill in the art to use higher concentration of acetic acid for extracting because the higher concentration of acetic acid solution may shorten the extraction time for producing the same effect as 0.5 M(3%) acetic acid. Thus, the teaching of the reference results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Applicant respectfully traverses the rejection because contrary to the Office Action's assertion, Miller et al. fails to teach extracting cartilage with a solution of acetic acid of 4% to obtain crude proteoglycan. Instead, Miller et al. teaches that a majority of proteglycan is removed with a **neutral** salt solvent and **not** an acetic **acid** solution. *See* Miller et al. at page 4094, lines 32-39. Miller et al. also teaches that the extraction procedure with the neutral salt solvent should be carried out for 5 successive days. *See id.* at line 35.

Although Miller et al. teaches a 0.5 M acetic acid solution, the acetic acid solution is only used **after** the neutral salt solvent has first been used to extract the cartilages slices of Miller et al. Based on the teachings of Miller et al., one of ordinary skill would not have had any suggestion or motivation to make the presently claimed method of using acetic acid given that Miller et al. states that the majority of proteglycan is removed in an extracting step using a **neutral** salt solvent.

Turning to the rule, the Federal Circuit held that a *prima facie* case of obviousness must establish: (1) some suggestion or motivation to modify the references; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed.

Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

In the present invention, independent claims 1-3 recite the limitation of extracting cartilage with a solution of acetic acid of 4% or more to obtain crude proteoglycan. On the other hand, Miller et al. specifically teaches that "the majority of the proteoglycan" is removed by daily extraction with a neutral salt solvent of 1.0 NaCl (pH 7.5, 0.05 M Tris) for 5 successive days. *See id.* at line 35. Only after the cartilage is extracted with a neutral salt solvent are the cartilage slices placed in a 0.5 M acetic acid solution.

Given the teaching in Miller et al. that the majority of proteglycan is extracted from cartilage slices with a neutral salt solvent of pH 7.5 for over five days, one of ordinary skill in the art would not have had any motivation or suggestion to use acid extraction to remove a majority of crude proteoglycan instead of a neutral salt solvent.

Moreover, one of ordinary skill in the art would also not have had any reasonable expectation of success in view of the teachings of Miller et al. that a neutral salt solvent is critical to removing the majority of the proteoglycan. Finally, there is absolutely no teaching or suggestion in Miller et al. that anything but a neutral salt solvent can be used to first remove a majority of the proteoglycan.

Accordingly, Applicant respectfully submits that the presently claimed invention is unobvious over the cited reference and respectfully requests reconsideration and withdrawal of the rejections of claims 1-3.

CONCLUSION

In light of the foregoing, Applicant submits that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

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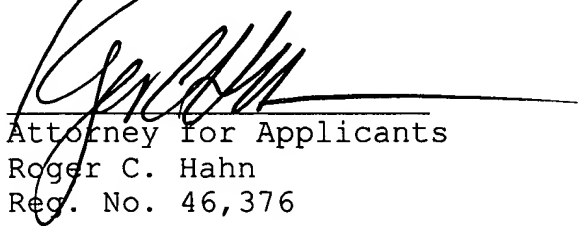

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